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ATTORNEY'S DOCKET NUMBER: 2004117-0024 (NEMC 284 US)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

**Applicant:** D. Bianchi *et al.* **Examiner:** NYA  
**Serial No.:** 10/577,341 **Group Art Unit:** NYA  
**Filing Date:** April 28, 2006  
**Corresp. to:** PCT/US2004/035929 **International Filing Date:** October 29, 2004  
**Earliest Priority:** 60/515,735 **Filing Date:** October 30, 2003  
**Title:** Prenatal Diagnosis Using Cell-Free Fetal DNA in Amniotic Fluid

Mail Stop Amendment  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

TRANSMITTAL LETTER


Enclosed are the following documents:

1. Form PTO-1449 (9 pages);
2. Information Disclosure Statement (6 pages);
3. Cited Art (87); and
4. Return Postcard.

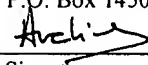
If any additional fees are required to be paid or if any overpayment has been made, please charge same to Deposit Account No. 03-1721

Respectfully submitted,

Dated: May 7, 2007

  
C. Hunter Baker, M.D., Ph.D.  
Registration Number: 46,533

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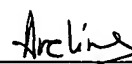
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May 7, 2007	
Date	Signature
	Beatrice M. Aveline, Ph.D.
Typed or Printed Name of person signing certificate	



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<b>Certificate of Mailing</b>	
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Sir:

**STATEMENT FILED PURSUANT TO THE  
DUTY OF DISCLOSURE UNDER 37 CFR §§1.56, 1.97 AND 1.98**

Pursuant to the duty of disclosure under 37 C.F.R. §§1.56, 1.97 and 1.98, Applicant requests consideration of this Information Disclosure Statement.

**Type of Statement**

The present Information Disclosure Statement is:

- [ X ] An *original* Information Disclosure Statement; or  
[ ] A *supplemental* Information Disclosure Statement.

Compliance with 37 CFR § 1.97

The present Information Disclosure Statement is being filed:

- ☒ Pursuant to 37 CFR § 1.97(b); no fee or certification is required:
- ☐ Within three months of the filing date of a national application other than a continued prosecution application under § 1.53(d);
  - ☐ Within three months of the date of entry of the national stage as set forth in § 1.491 in an international application;
  - ☒ Before the mailing of a first Office action on the merits; or
  - ☐ Before the mailing of a first Office action after the filing of a request for continued examination under § 1.114.
- ☐ Pursuant to 37 CFR § 1.97(c) after the dates listed above but before the mailing date of any of a final action under § 1.113, a notice of allowance under § 1.311, or an action that otherwise closes prosecution in the application; Applicant hereby *either*:
- ☐ Certifies that *either*:
    - ☐ each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement; or
    - ☐ That no item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the

knowledge of the person signing the certification after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in § 1.56(c) more than three months prior to the filing of the information disclosure statement.; or

☐ Includes herewith the fee set forth in § 1.17(p).

☐ Pursuant to 37 CFR § 1.97(d), after the mailing date of any of a final action under § 1.113, a notice of allowance under § 1.311, or an action that otherwise closes prosecution in the application; Applicant hereby *both*:

☐ Certifies that *either*:

☐ each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement; or

☐ That no item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing the certification after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in § 1.56(c) more than three months prior to the filing of the information disclosure statement.; and

### Content of the Information Disclosure Statement

Applicant hereby makes of record in the above-identified application the reference(s) listed on the attached form PTO-1449 (modified). The order of presentation of the references should not be construed as an indication of the importance of the references.

Applicant includes copies of references as indicated below:

- ☒ [X] A copy of each cited reference not indicated with a \* is included;
- ☐ [ ] Copies of references indicated with a † on the attached form PTO-1449 are not included pursuant to 37 CFR § 1.98(d) because they were previously provided/cited to the United States Patent Office in an Information Disclosure Statement that complies with 37 CFR § 1.98(a)-(c) and was submitted in the following patent application that is relied upon in the present case for an earlier effective filing date under 35 USC § 120:
- ☐ [ ] Copies of English translations of one or more non-English references are included.

Applicant hereby makes the following additional information of record in the above-identified application:

Applicant certifies that the Information Disclosure Statement *either*:

- ☒ [X] Does not contain non-English language citations;
- ☐ [ ] Does contain non-English language citations, of which an English language translation of the Abstract for each is provided herein:
- ☐ [ ] Includes one or more translations of a non-English citation.

## Remarks

The submission of this Information Disclosure Statement should not be construed as a representation that a search has been made.

The submission of this Information Disclosure Statement shall not be construed to be an admission that the information cited in the statement is, or is considered to be, material to patentability as defined in § 1.56(b) .

The submission of this Information Disclosure Statement shall not be construed as a representation that the information cited in the Statement is, or is considered to be, in fact, prior art as defined by 35 U.S.C. §102.

It is respectfully requested that:

1. The Examiner consider completely the cited information, along with any other information, in reaching a determination concerning the patentability of the present claims;
2. The enclosed form PTO-1449 be signed by the Examiner to evidence that the cited patent(s) and publication(s) has (have) been fully considered by the Patent and Trademark Office during the examination of this application; and
3. The citations for the patent(s) and publication(s) be printed on any patent which issues from this application.

Notwithstanding any statements by Applicants, the Examiner is urged to form his or her own conclusions regarding the relevance of the cited reference(s).

Respectfully submitted,

Dated: 5/7, 2007



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C. Hunter Baker, M.D., Ph.D.  
Registration Number: 46,533

CHOATE, HALL & STEWART, LLP  
PATENT GROUP  
Two International Place  
Boston, MA 02110  
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Fax: 617-248-4000

MAY 10 2007

## INFORMATION DISCLOSURE STATEMENT

(Use several sheets if necessary)

Applicant:

Bianchi, *et al.*

Filing Date:

April 28, 2006

Group:

TBA

## U.S. PATENT DOCUMENTS

Examiner's Initials	U.S. Patent No.	Applicant	Issue Date	Class	Subclass
	* 4,355,153	Radici et al.	October 19, 1982	528	191
	* 4,458,066	Caruthers et al.	July 3, 1984	536	25.34
	* 4,652,613	Collins et al.	March 24, 1987	525	69
	* 4,683,195	Mullis et al.	July 28, 1987	435	6
	* 4,683,202	Mullis	July 28, 1987	435	91.2
	* 4,774,339	Haugland et al.	September 27, 1988	548	405
	* 4,800,159	Mullis et al.	January 24, 1989	435	91.2
	* 5,047,519	Hobbs et al.	September 10, 1991	536	27.14
	* 5,068,269	Diamantoglou	November 26, 1991	524	35
	* 5,143,854	Pirrung et al.	September 1, 1992	436	518
	* 5,151,507	Hobbs et al.	September 29, 1992	536	26.7
	* 5,187,288	Kang et al.	February 16, 1993	548	110
	* 5,227,487	Haugland et al.	July 13, 1993	546	15
	* 5,248,782	Haugland et al.	September 28, 1993	548	110
	* 5,266,489	Rey-Senelongue et al.	November 30, 1993	435	320.1
	* 5,286,486	Payne et al.	February 15, 1994	424	93.2
	* 5,288,625	Hadlaczky	February 22, 1994	435	449
	* 5,288,641	Roizman	February 22, 1994	435	320.1
	* 5,434,049	Okano et al.	July 18, 1995	435	6
	* 5,501,979	Geller et al.	March 26, 1996	435	320.1
	* 5,539,517	Cabib et al.	July 23, 1996	356	456
	* 5,556,752	Lockhart et al.	September 17, 1996	435	6
	* 5,614,386	Metzker et al.	March 25, 1997	435	91.1
	* 5,632,957	Heller et al.	May 27, 1997	422	68.1
	* 5,635,351	Feuerstein et al.	June 3, 1997	435	6
	* 5,665,549	Pinkel et al.	September 9, 1997	435	6
	* 5,700,637	Southern et al.	December 23, 1997	435	6
	* 5,714,386	Roederer	February 3, 1998	436	546
	* 5,721,098	Pinkel et al.	February 24, 1998	435	6



**INFORMATION DISCLOSURE STATEMENT***(Use several sheets if necessary)*Applicant:  
Bianchi, *et al.*Filing Date:  
April 28, 2006Group:  
TBA

	* 5,721,118	Scheffler	February 24, 1998	435	69.1
	* 5,744,305	Fodor et al.	April 28, 1998	435	6
	* 5,770,456	Holmes	June 23, 1998	436	518
	* 5,776,745	Ketner et al.	July 7, 1998	435	477
	* 5,790,727	Dhadwal et al.	August 4, 1998	385	38
	* 5,795,557	Pajonk et al.	August 18, 1995	790	727,
	* 5,800,992	Fodor et al.	September 1, 1998	435	6
	* 5,807,522	Brown et al.	September 15, 1998	422	50
	* 5,830,645	Pinkel et al.	November 3, 1998	435	6
	* 5,843,767	Beattie	December 1, 1998	435	287.1
	* 5,846,708	Hollis et al.	December 8, 1998	435	6
	* 5,856,097	Pinkel et al.	January 5, 1999	435	6
	* 5,856,174	Lipshutz et al.	January 5, 1999	435	286.5
	* 5,874,259	Szybalski	February 23, 1999	435	91.1
	* 5,880,473	Ginestet	March 9, 1999	250	458.1
	* 5,922,617	Wang et al.	July 13, 1999	436	518
	* 5,939,261	Loewy et al.	August 17, 1999	435	6
	* 5,943,129	Hoyt et al.	August 24, 1999	356	318
	* 5,959,098	Goldberg et al.	September 28, 1999	536	25.3
	* 5,965,362	Pinkel et al.	October 12, 1999	435	6
	* 5,965,452	Kovacs	October 12, 1999	436	149
	* 5,976,790	Pinkel et al.	November 2, 1999	435	6
	* 5,981,175	Loring et al.	November 9, 1999	435	6
	* 5,994,063	Metzker et al.	November 30, 1999	435	6
	* 6,013,440	Lipshutz et al.	January 11, 2000	435	6
	v6,022,963	McGall et al.	February 8, 2000	536	25.3
	* 6,024,872	Mahendran et al.	February 15, 2000	210	500.25
	* 6,025,155	Hadlaczky et al.	February 15, 2000	435	69.1
	* 6,027,709	Little et al.	February 22, 2000	424	1.65
	* 6,045,996	Cronin et al.	April 4, 2000	435	6
	* 6,048,457	Kopaciewicz et al.	April 11, 2000	210	321.6
	* 6,048,695	Bradley et al.	April 11, 2000	435	6

<b>Form PTO-1449</b> <b>(REV. 8-83)</b>			<b>U.S. Department of Commerce</b> <b>Patent and Trademark Office</b>			<b>Attorney Docket</b> 2004117-0024		<b>In re Application No.</b> 10/577,341	
<b>INFORMATION DISCLOSURE STATEMENT</b> <i>(Use several sheets if necessary)</i>						Applicant: Bianchi, <i>et al.</i>			
						Filing Date: April 28, 2006		Group: TBA	
	* 6,049,380	Goodwin et al.	April 11, 2000	356	317				
	* 6,054,270	Southern	April 25, 2000	435	6				
	* 6,054,279	Nadeau et al.	April 25, 2000	435	6				
	* 6,055,325	Garini et al.	April 25, 2000	382	129				
	* 6,060,324	Naguib	May 9, 2000	436	7				
	* 6,063,338	Pham et al.	May 16, 2000	422	61				
	* 6,066,459	Garini et al.	May 23, 2000	435	6				
	* 6,077,697	Hadlaczky et al.,	June 20, 2000	435	6				
	* 6,096,817	Mc Namara	August 1, 2000	524	406				
	* 6,140,044	Besemer et al.	October 31, 2000	435	6				
	* 6,143,495	Lizardi et al.	November 7, 2000	435	6				
	* 6,159,685	Pinkel et al.	December 12, 2000	435	6				
	* 6,183,957	Cole et al.	February 6, 2001	435	6				
	* 6,191,425	Imai	February 20, 2001	250	458.1				
	* 6,197,501	Cremer et al.	March 6, 2001	435	6				
	* 6,235,504	Zhang et al.	May 22, 2001	435	91.2				
	* 6,252,664	Barbera-Guillem	June 26, 2001	356	417				
	* 6,258,606	Kovacs	July 10, 2001	436	149				
	* 6,261,776	Pirrung et al.	July 17, 2001	435	6				
	* 6,277,489	Abbott et al.	August 21, 2001	428	403				
	* 6,277,581	O'Brien; et al.	August 21, 2001	435	6				
	* 6,277,621	Horsburgh et al.	August 21, 2001	435	235.1				
	* 6,277,628	Johann et al.	August 21, 2001	435	287.2				
	* 6,294,338	Nunomura	September 25, 2001	435					
	* 6,294,331	Ried et al.	September 25, 2001	435	6				
	* 6,335,167	Pinkel et al.	January 1, 2002	435	6				
	* 6,365,349	Moynihan et al.	April 2, 2002	435	6				
	* 6,387,626	Shi et al.	May 14, 2002	435	6				
	* 6,458,584	Mirzabekov et al.	October 1, 2002	435	287.2				
	* 6,503,711	Krull et al.	January 7, 2003	435	6				
	* 6,516,276	Ghandour et al.	February 4, 2003	702	27				
	* 6,521,465	Stimpson	February 18, 2003	436	518				

<b>Form PTO-1449</b> <b>(REV. 8-83)</b>		U.S. Department of Commerce Patent and Trademark Office		Attorney Docket 2004117-0024		In re Application No. 10/577,341	
<b>INFORMATION DISCLOSURE STATEMENT</b> <i>(Use several sheets if necessary)</i>				Applicant: Bianchi, <i>et al.</i>			
				Filing Date: April 28, 2006		Group: TBA	
	* 6,558,907	Koroulis et al	May 6, 2003	435	6		
	* 6,562,565	Pinkel et al.	May 13, 2003	435	6		
	* 6,576,424	Fodor et al.	June 10, 2003	435	6		
	* 6,587,579	Bass	July 1, 2003	382	141		
	* 6,589,726	Butler et al.	July 8, 2003	435	4		
	* 6,594,432	Chen et al	July 15, 2003	385	133		
	* 6,599,693	Webb	July 29, 2003	435	4		
	* 6,600,031	Fodor et al.	July 29, 2003	536	24.3		
	* 6,613,893	Webb	September 2, 2003	536	25.3		
<b>U.S. PATENT APPLICATIONS</b>							
Examiner's Initials:	Serial Number:	Applicant:	Filing Date:	Group:	Art Unit:		
<b>FOREIGN PATENT DOCUMENTS</b>							
Examiner's Initials	Document No.	Country	International Publication Date	Translation			
				Yes	No		
	EP 1 026 260	Europe	August 9, 2000		X		
	EP 1 134 293	Europe	September 19, 2001		X		
<b>OTHER DOCUMENTS</b>							
Examiner's Initials	Citation (Including Author, Title, Date, Pertinent Pages, Etc.)						
	Aljanabi and Martinez, "Universal and rapid salt-extraction of high quality genomic DNA for PCR-based techniques", <i>Nucl. Acids Res.</i> , 1997, <b>25</b> : 4692-4693.						
	Amicucci <i>et al.</i> , "Prenatal diagnosis of myotonic dystrophy using fetal DNA obtained from maternal plasma", <i>Clin. Chem.</i> , 2000, <b>46</b> : 301-302.						
	Belousov <i>et al.</i> , "Sequence-specific targeting and covalent modification of human genomic DNA", <i>Nucleic Acids Res.</i> , 1997, <b>25</b> : 3440-3444.						
	Bianchi <i>et al.</i> , "Detection of fetal cells with 47,XY,+21 karyotype in maternal peripheral blood", <i>Hum. Genet.</i> , 1992, <b>90</b> : 368-370.						
	Bianchi <i>et al.</i> , "Erythroid-specific antibodies enhance detection of fetal nucleated erythrocytes in maternal blood", <i>Prenatal. Diagn.</i> , 1993, <b>13</b> : 293-300.						
	Bianchi <i>et al.</i> , "PCR quantitation of fetal cells in maternal blood in normal and aneuploid						

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		<table border="1"> <tr> <td data-bbox="27 346 243 388"></td> <td data-bbox="243 346 1562 388">           pregnancies", <i>Am. J. Hum. Genet.</i>, 1997, <b>61</b>: 822-829.         </td> </tr> <tr> <td data-bbox="27 388 243 472"></td> <td data-bbox="243 388 1562 472">           Bianchi, "Fetal DNA in maternal plasma: the placental barrier thins", <i>Am. J. Hum. Genet.</i>, 1998, <b>62</b>: 763-764.         </td> </tr> <tr> <td data-bbox="27 472 243 556"></td> <td data-bbox="243 472 1562 556">           Bianchi <i>et al.</i>, "Large amounts of cell-free fetal DNA are present in amniotic fluid", <i>Clin. Chem.</i>, 2001, <b>47</b>: 1867-1869.         </td> </tr> <tr> <td data-bbox="27 556 243 682"></td> <td data-bbox="243 556 1562 682">           Bianchi <i>et al.</i>, "Fetal gender and aneuploidy detection using fetal cells in maternal blood: analysis of NIFTY I data. National Institute of Child Health and Development Fetal Cell Isolation Study", <i>Prenat. Diagn.</i>, 2002, <b>22</b>: 609-615.         </td> </tr> <tr> <td data-bbox="27 682 243 808"></td> <td data-bbox="243 682 1562 808">           Bohmer <i>et al.</i>, "Differential development of fetal and adult haemoglobin profiles in colony culture: isolation of fetal nucleated red cells by two-colour fluorescence labelling", <i>Br. J. Haematol.</i>, 1998, <b>103</b>: 351-360.         </td> </tr> <tr> <td data-bbox="27 808 243 892"></td> <td data-bbox="243 808 1562 892">           Bowtell, "Options available--from start to finish--for obtaining expression data by microarray", <i>Nature Gen.</i>, 1999, Supp. <b>21</b>:25-32.         </td> </tr> <tr> <td data-bbox="27 892 243 934"></td> <td data-bbox="243 892 1562 934">           Brazma and Vilo, "Gene expression data analysis", <i>FEBS Lett.</i>, 2000, <b>480</b>: 17-24.         </td> </tr> <tr> <td data-bbox="27 934 243 1018"></td> <td data-bbox="243 934 1562 1018">           Brison <i>et al.</i>, "General method for cloning amplified DNA by differential screening with genomic probes", <i>Mol. Cell. Biol.</i>, 1982, <b>2</b>: 578-587.         </td> </tr> <tr> <td data-bbox="27 1018 243 1144"></td> <td data-bbox="243 1018 1562 1144">           Bryndorf <i>et al.</i>, "Rapid prenatal diagnosis of chromosome aneuploidies by interphase fluorescence in situ hybridization: a one-year clinical experience with high-risk and urgent fetal and postnatal samples", <i>Acta Obstet. Gynecol. Scand.</i>, 2000, <b>79</b>: 8-14.         </td> </tr> <tr> <td data-bbox="27 1144 243 1228"></td> <td data-bbox="243 1144 1562 1228">           Chan <i>et al.</i>, "Size distributions of maternal and fetal DNA in maternal plasma", <i>Clin. Chem.</i>, 2004, <b>50</b>: 88-92.         </td> </tr> <tr> <td data-bbox="27 1228 243 1312"></td> <td data-bbox="243 1228 1562 1312">           Chen <i>et al.</i>, "Fetal DNA in maternal plasma: the prenatal detection of a paternally inherited fetal aneuploidy", <i>Prenat. Diag.</i>, 2000, <b>20</b>: 355-357         </td> </tr> <tr> <td data-bbox="27 1312 243 1396"></td> <td data-bbox="243 1312 1562 1396">           Chen <i>et al.</i>, "Fetal DNA analyzed in plasma from a mother's three consecutive pregnancies to detect paternally inherited aneuploidy", <i>Clin. Chem.</i>, 2001, <b>47</b>: 937-939.         </td> </tr> <tr> <td data-bbox="27 1396 243 1480"></td> <td data-bbox="243 1396 1562 1480">           Cheung <i>et al.</i>, "Prenatal diagnosis of sickle cell anaemia and thalassaemia by analysis of fetal cells in maternal blood", <i>Nature Genet.</i>, 1996, <b>14</b>: 264-268.         </td> </tr> <tr> <td data-bbox="27 1480 243 1522"></td> <td data-bbox="243 1480 1562 1522">           Cheung <i>et al.</i>, "Making and reading microarrays", <i>Nature Genet.</i>, 1999, <b>21</b>: 15-19.         </td> </tr> <tr> <td data-bbox="27 1522 243 1606"></td> <td data-bbox="243 1522 1562 1606">           Daniely <i>et al.</i>, "Detection of chromosomal aberration in fetuses arising from recurrent spontaneous abortion by comparative genomic hybridization", <i>Hum. Reprod.</i>, 1998, <b>13</b>: 805-809.         </td> </tr> <tr> <td data-bbox="27 1606 243 1690"></td> <td data-bbox="243 1606 1562 1690">           De la Cruz <i>et al.</i>, "Low-false positive rate of aneuploidy detection using fetal cells isolated from maternal blood", <i>Fetal Diagn. Ther.</i>, 1998, <b>13</b>: 380.         </td> </tr> <tr> <td data-bbox="27 1690 243 1774"></td> <td data-bbox="243 1690 1562 1774">           DeRisi <i>et al.</i>, "Use of a cDNA microarray to analyse gene expression patterns in human cancer", <i>Nature Genet.</i>, 1996, <b>14</b>: 457-460.         </td> </tr> <tr> <td data-bbox="27 1774 243 1879"></td> <td data-bbox="243 1774 1562 1879">           Di Naro <i>et al.</i>, "Prenatal diagnosis of beta-thalassaemia using fetal erythroblasts enriched from maternal blood by a novel gradient", <i>Mol. Hum. Reprod.</i>, 2000, <b>6</b>: 571-574.         </td> </tr> </table>			pregnancies", <i>Am. J. Hum. Genet.</i> , 1997, <b>61</b> : 822-829.		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